Remarks

Non-Statutory Subject Matter Rejection:

Applicant has taken note of Examiner's suggestions and has corrected claims 2 and 3 such that non-statutory material is not included. "Implanted" has been replaced by "implantable" and the claims therefore, should not contain any non-statutory matter.

Rejection Under 35 U.S.C. § 102:

Applicant acknowledges Examiner's confusion with the terminology "coordinated electrical stimulation" in the Remarks section of the response to the first Office action. The present invention does not electrically stimulate the heart; the present invention mechanically massages the heart so as to induce the heart to re-establish its own electrical rhythm and contracting sequence. This is what was meant by "coordinated electrical stimulation." No electrical stimulation of the heart is either contemplated or possible by means of the present invention. The electrical activity contemplated is that of sensing cardiac activity and responding in accordance with, e.g., Claim 7.

In addition, Applicant respectfully submits that Examiner may not have fully understood Applicant's response to the previous office action in regard to the Examiner's anticipation rejection in view of Millbocker US Patent No. 6,602,182. Applicant stated in the previous response that the Millbocker device could not function in the same manner (and this is structurally different) as the present invention.

The present invention causes fluid to flow in one direction, from the apex to the base of the heart. The fluid within the chamber array does not flow back down the cardiac wall, but continues past the base to a reservoir. Please note that claim 1 has been amended to reflect this emphasis. Contraction is a continuous upward motion. This upward-only movement by the chamber array prevents blood from within the heart to back-flow into the ventricles. During diastole, blood fills the ventricles. During systole, the chamber array, starting from the apex, contracts the heart muscle to push blood up through the aorta. There is no downward pull to cause the blood to back-flow into the ventricles in operation of this invention.

In contrast, the Millbocker device, in all embodiments taught or suggested, will cause back-flow into the ventricles. The Millbocker device is configured such that the fluid output of the inflatable elements follows the same path as the fluid input, such that the flow travels back down the cardiac wall. Because the same path is followed, forces are created such that pressure is placed on the heart to induce back-flow into the ventricles.

These are other distinctions from the Millbocker patent.

In the background of the invention Millbocker states, "A volume of inflating fluid or gas is required to displace an equal volume of blood." Millbocker does not describe how he gets around this issue to use less volume without requiring higher pressures.

Secondly, under the summary of invention Millbocker states, "the control module can include an internal electronic controller for generating a suitably shaped pressure wave..." In contrast, the present invention, in one embodiment, uses a Bourdon tube in which the volume into the tube which is moved is less than the area displaced by the Bourdon tube deflection.

Thirdly, as Millbocker points out in his summary of invention, his device generates a pressure wave to displace the heart whereas the present invention provides, as noted above, a mechanism for a Bourdon tube displacement.

The Millbocker device is described, "...to sense the heart's electrical signals and synchronize pump activation". He does not describe any mechanism for stimulating the heart muscle to contract on its own. An important and frequent component of heart failure is that the contraction of the heart is less efficient since the muscle is not stimulated in its normal optimum pathway. It also disturbs the valvular function of the heart thereby further aggravating the heart failure. The Millbocker device in no way addresses this aspect of heart failure. It is important to reference the activity of the heart muscle itself in this situation and by this it is meant that a device that causes the heart to contract where there is active muscular contraction. This is an active device and the present invention's device provides for phased array or a coordinated electrical stimulation of the heart to restore its normal contraction sequence bringing about a normalization of the active phase of contraction.

An external device applied to the heart muscle, which does not cause intrinsic contraction of the muscle, refers to a passive contraction in reference again to the activity of the heart muscle. The Millbocker device is purely a passive device and does not stimulate heart muscle activity but merely applies a pressure to the outside of the heart.

"A pressurized volume of fluid of sufficient size to provide a flow at nearly constant pressure during systole and to provide a flow away from the heart assist device at nearly contact vacuum (i.e., at a pressure less than ambient) during iastole." This is a bi-directional pump which is completely different than the Bourdon tube concept. The significance of this is apparent at Column 8, Line 65 of Millbocker where it says "so that in the event of failure, the device does not interfere with the natural pumping action of the heart" and "should not encumber the natural function of the heart moreover in the event of failure, the device should not interfere with the heart." Millbocker's solution to not interfering with the natural function of the heart in the state of device failure is addressed in Column 26, Line 28 where it references U.S. patent 5,713,954 "teaches of a subdermal port for draining the pumping unit in the event of failure of the hydraulic pumping capacity of the heart. Such a subdermal port can be accessed through a skin puncture with an array of 15 gauge needles."

This again is totally different than the present invention in which during device failure the Bourdon tube returns to its natural state, which is away from the heart. One experienced in the art can readily see that the Millbocker device requires that recipients of the Millbocker device are required to travel wherever they go with an assortment of syringes and 15 gauge needles in the event of device failure whereas with the present invention that is not necessary.

Again the difference in the concept between active and passive devices in reference to the state of the heart muscle itself is highlighted in Column 25, Line 62, "Synchronization is achieved by sensing the natural rhythm of the heart or through implantable pacer electrodes." Again in Column 26, Line 9 "atrial sensing is accomplished with a lead sutured to the right atrial appendage. Alternatively, in the case of R-wave sensing, a corkscrew electrode is attached to the ventricle near the apex at a location free of wrap contact."

The present invention's device is uniquely different in that it encompasses a phased array of electrodes that not only sense the electrical activity of the heart but also determines when the electrical dispersion is abnormal and restores it back to a normal physiologic contraction sequence with stimulation of the heart muscle in an active sense, which is then augmented by the external application of pressure via e.g., the Bourdon tube, on the heart muscle.

It follows that Millbocker does not and could not anticipate the invention of Claims 1-8.

The above amendments to the claims merely clarify the coverage and would not involve any additional search. Entry and allowance of all claims of the proposed claim amendments in accordance with Rule 116 is earnestly solicited.

Conclusion

It is believed that all claims are now in condition for allowance. An early notice of same is earnestly solicited.

Respectfully submitted,

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